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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,124

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Dominique M. Freeman

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10/04/2010

Goodwin Procter LLP

Attn: Patent Administrator

135 Commonwealth Drive

Menlo Park, CA 94025-1105

EXAMINER

EDWARDS, LYDIA E

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

10/04/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/541,124	Applicant(s) FREEMAN ET AL.	
	Examiner LYDIA EDWARDS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 28, 29 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 28, 29 and 34-40 is/are allowed.
- 6) ☒ Claim(s) 1-4, 24-25 and 32-33 is/are rejected.
- 7) ☒ Claim(s) 5-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/7/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

As previously discussed in the office action dated 6/9/2010, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Moreover, Simons discloses wherein an absorbent material [218] or an adjoined surface can serve as a test area [220] for the analyte detecting member [210] for measurements of blood characteristics, such as glucose measurements. As in existing glucose measurements techniques, a chemical reaction occurs when blood contacts the test area (Col 8, 19-25). The examiner deems Simons fully capable of creating a chemical reaction that produces a type of luminescence such as bioluminescence, chemoluminescence, fluorescence, etc. thereby providing an optical indicator.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 24-25, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al. (U.S. 6036924) in view of Lum et al. (GB 2335990) further in view of Betts et al. (US 5405510).

Regarding Claims 1, 4, 24 and 32-33, Simons et al. ('924) discloses a cartridge (246) having a plurality of analyte detecting members (210) mounted on said cartridge, the cartridge comprising cavities (wells, 44), a plurality of penetrating members (216 connected to 224) which are contained at least partially in the cavities and are slidably movable to extend outward from the openings on the cartridge (col. 5 lines 16-26). Simons et al. also discloses a plurality of

Art Unit: 1797

chambers each associated with a cavity that are positioned along an outer periphery of the cartridge. An analyte detecting member is associated with each chamber and forms a portion of one wall of the plurality of chambers (Fig. 3A, 220 and col. 8 lines 19-29). Simons et al. discloses that the test area can be the absorbent material 218 or the surface beneath it which is a wall of the chamber. Simons et al. discloses the invention as stated above regarding claim 1 and further discloses that the chamber is positioned substantially adjacent an outer periphery of the cartridge (Fig. 6D) and at least one opening in one of the chambers which leads fluid along a fluid path toward an analyte detecting member (col. 8 lines 19-22 and lines 29-35 and col. 7 lines 40-49).

Simons fails to disclose a position sensor coupled to the plurality of penetrating members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface.

Lum et al. ('990) discloses that it is old and well known in the art to use a position sensor coupled to a penetrating member, the position sensor utilizing the position information of the penetrating member to determine the depth of penetration through the skin. In particular, Lum et al. discloses a penetrating member that uses a sensor that senses the different impedance values of the different layers of skin to determine information on which layer of skin the penetrating member is positioned within (p. 3, lines 4-7). Lum et al. further discloses that this information helps to minimize the trauma and pain of over-penetration as well as avoid the frustration and pain of unsuccessful blood sampling because of inadequate penetration (p. 3, lines 16-23). Lum et al. discloses that these advantages are especially pertinent to patients such as diabetics, who

Art Unit: 1797

have to sample blood often (p. 1, lines 22-23). Simons et al. disclose that the cartridge of their body fluid sampling device may be used in conjunction with a glucometer (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. to include a position sensor coupled to the plurality of penetrating members, the position sensor utilizing position information of a penetrating member to determine a depth of penetration through a skin surface as made obvious by Lum et al. in order to avoid the problems associated with over-penetration or inadequate penetration.

Simons fails to disclose a memory on said device.

Betts et al. ('510) discloses memory on a analyte measuring system for fluid samples (Col 5, lines 16-65 and Col 6, line 34-59)

It would have been obvious to one of ordinary skill in the art to modify the device of Simons et al. and Lum et al. with a memory on the device as taught by Betts et al. to employ a means for calibration and analysis of the samples.

Regarding Claim 2, Simons ('924), discloses wherein the cartridge does not include any penetrating members (Figures 6b and 6d).

Regarding Claim 3, Simons ('924), discloses wherein said cartridge has a radial disc shape (Figure 6c and 6d).

Regarding Claim 25, Simons ('924), discloses multiple cartridges comprising penetrating members in cavities on said cartridge (Figures 1b, 4b and 5a).

Allowable Subject Matter

Claims 28, 29 and 34-40 are allowed.

Regarding Claim 28, prior art fails to disclose a method for determining a concentration of an analyte in body fluid, comprising: collecting a sample of body fluid of about 500 nL or less; covering an electrochemical sensor with at least a portion of the sample; determining the concentration of the analyte in the sample using a optical technique.

Regarding Claim 29, prior art fails to disclose a method comprising: providing a cartridge having a plurality of wells; depositing an emulsion in the wells; scraping away emulsion from tops of the wells, in order to level the amount of emulsion in each well.

Regarding Claims 34-40 prior art fails to disclose the device of claim 33 further comprising an optical system.

Claims 5-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYDIA EDWARDS/
Examiner
Art Unit 1797

LE

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797